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Andrew Ian Cooper

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MICHAEL BEST & FRIEDRICH LLP
100 E WISCONSIN AVENUE
Suite 3300
MILWAUKEE, WI 53202

EXAMINER

KRYLOVA, IRINA

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1764

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/587,734	Applicant(s) COOPER ET AL.	
	Examiner IRINA KRYLOVA	Art Unit 1764	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 18 March 2011.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,3-9 and 21 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,3-9 and 21 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>03/18/11</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on March 18, 2011 has been entered.

Response to Amendment

2. The amendment to instant claim 1 is acknowledged. Specifically, claim 1 has been amended to include the limitations of the porous bodies having pores from complete sublimation of solid ice from water phase of the emulsion and from the complete sublimation of the oil phase of the emulsion, and further the oil of the oil phase of the emulsion being volatile. These limitations were not previously presented and were taken from instant specification (see p. 10, lines 4-7 stating that all frozen liquid medium being removed by sublimation; and p. 10, lines 26- page 11, line 4 stating the list of organic solvents being used as the discontinuous phase). In light of the amendment, all previous rejections are withdrawn. The new grounds of rejections are set forth below. Though the new grounds of rejections are based on the same prior art as previously applied, however, they have been suitably framed to better address the newly introduced limitations and Applicant's arguments.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. Claim 1 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The amended claim 1 recites the oil of the oil phase of the emulsion being volatile. However, instant specification does not provide a support for this limitation. Though instant specification in col. 10, lines 26 through p. 11, line 4 recites the list of organic solvents that could be used as the discontinuous oil phase and which appear to be volatile (e.g. having boiling point of 50-260°C), however, instant specification does not state that the discontinuous oil phase should be volatile but rather just being removable by sublimation.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. Claims 1, 3-9, 21 are rejected under 35 U.S.C. 103(a) as being unpatentable over **Gregory et al** (US 4,371,516) in view of **Haynes et al** (US 5,660,857), **Gross** (US 5,354,290) and **Schneider et al** (US 6,403,057).

5. As to instant claim 1, **Gregory et al** discloses shaped articles having a porous open matrix network of water-soluble carrier (col. 2, lines 37-40), the articles carrying a chemical (also, as to instant claim 7), the article being capable of being rapidly disintegrated by water (col. 1, lines 58-64), wherein the article comprise:

A) a polysaccharide, polyvinyl alcohol, polyvinyl pyrrolidone or mixtures thereof;

B) a surfactant, such as polyoxyethylene sorbitan monooleate (col. 4, lines 5-8).

The surfactant prevents the freeze dried product from sticking to the surface of the mold and also aids in the dispersion of the chemical (col. 4, lines 1-7).

The shaped articles are produced by freeze drying of a composition (col. 3, lines 63-65).

The shaped articles comprise cylindrical or other shapes (col. 4, lines 8-12).

6. Though **Gregory et al** does not explicitly state the porous system having an intrusion volume measured by mercury porosimetry of at least about 3 ml/g, however, since the porous system of **Gregory et al** comprises the same composition as that claimed in the instant invention, and the porous system of **Gregory et al** is produced by the same process as that claimed in the instant invention, therefore, the porous system

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of **Gregory et al** will intrinsically comprise the intrusion volume measured by mercury porosimetry being the same as that claimed in the instant invention.

7. Though **Gregory et al** does not specify the amount of surfactant present in the composition, and the provided examples specify the amount of surfactant being less than 5% (see Example 5), nevertheless, since **Gregory et al** stated that the surfactant aids in dispersion of the chemical and prevents the freeze dried product from sticking to mold, therefore, the specific amount of the surfactant present in the composition will become a result effective variable, therefore, it would have been obvious to one skilled in the art at the time of the invention was made, to make variations in the content of the surfactant to obtain the desired degree of dispersing of the chemical in aqueous medium. *In re Boesch*, 617 F.2d 272, 205 USPQ 215 (CCPA 1980) (MPEP 2144.05 II).

8. It is noted that the limitation of claim 1 “oil-in-water emulsion-formed lattice” is a product by process limitation. For purposes of examination, product-by-process claims are not limited to the manipulation of the recited steps, only the structure implied by the steps. See MPEP 2113. In the present case, the recited steps imply a structure having porous bodies containing hydrophobic material. The reference suggests such a product.

9. Thus, **Gregory et al** discloses that shaped articles, which appear to be produced in a mould (col. 4, lines 29-30; col. 3, lines 60-61) and thus are being moulded articles, are

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prepared by subliming solvent from composition comprising the chemical and a solution of a carrier material in a solvent (col. 3, lines 57-68), wherein the solvent is preferably water but it may contain a co-solvent to improve solubility of the chemical (col. 3, lines 68-69; col. 4, lines 1-2). Thus, it would have been obvious to a skilled artisan that depending on the specific drug, i.e. hydrophilic or hydrophobic, a specific co-solvent appropriate for increasing solubility of that drug, should be used. **Gregory et al** discloses the use of such drug as ethynyl oestradiol (col. 3, lines 36). Oestradiol is known in the art to be a hydrophobic drug (as disclosed by **Haynes et al** in col. 4, lines 34-36).

10. Though **Gregory et al** does not explicitly state the lattice being formed from oil-in-water emulsion, wherein the oil of the oil phase is volatile, and specify the porous bodies having two types of pores, as required by instant claim 1, and the polymeric material being hydroxyethylcellulose, as required by instant claim 4, however, **a) Haynes et al** discloses a process for preparing a composite comprising preparing an oil-in-water-emulsion followed by freeze drying the emulsion (col. 2, lines 40-42) to form a sponge (col. 2, lines 30-31). The oil phase is used for dissolving oestradiol hydrophobic drug (col. 4, lines 34-36; col. 2, lines 50-51). The composition comprises sorbitan ester and polysaccharide emulsifiers (col. 4, lines 1-8). **Haynes et al** teaches that composites containing low quantities of the oleaginous material are made by dissolving the oleaginous material in a volatile organic solvent, such as n-hexane, prior

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to forming the emulsion, which aids the dispersion of the oleaginous material throughout the matrix; the volatile solvent is then lost during drying process (col. 3, lines 57-65).

b) **Gross** discloses porous structures comprising water-soluble polymeric material selected from the group consisting of polyacrylic acid and and hydroxyethylcellulose (also, as to instant claims 3-4, cited in col. 12, lines 14-32), formed by a process comprising forming an oil-in-water suspension comprising water phase and an oil phase of a volatile organic compound, followed by drying, so that while drying the volatile organic compound volatilizes thus creating pores in the polymeric structure (Abstract; col. 2, lines 60-col. 3, line 10);

c) **Schneider et al** discloses microcapsules made by i) making an oil-in-water emulsion further containing surfactants, such as polyvinyl alcohol, sorbitan esters and ethoxylated glycerides, used to stabilize the emulsion (col. 4, lines 34-48, also, as to instant claims 5-6), the emulsion comprising organic solvents such as cyclohexane, chloroform (col. 7, lines 38-48); followed by ii) freezing the emulsion and iii) subjecting the emulsion to reduced pressure to effect lyophilization, i.e. removal by sublimation of the organic solvent from the droplets and of water of the carrier phase (col. 4, lines 50-63). Thus, since the process of **Schneider et al** is identical to that claimed in the instant invention, therefore, it would have been obvious to a one of ordinary skill in the art that sublimation of both water phase and volatile organic phase would intrinsically lead to formation of two types of voids, i.e. from the sublimation of water and from the sublimation of volatile organic solvent as well.

11. Since **Gregory et al** discloses the shaped articles having a porous open matrix network of water-soluble carrier, the articles carrying a chemical and the article being capable of being rapidly disintegrated by water, and being produced by freeze drying of solvent system but does not explicitly recite the porous matrix being prepared from oil-in-water emulsion; and **Haynes et al**, **Gross** and **Schneider et al** disclose similar processes for making void-containing composites but further specify the composites being produced by first making a oil-in-water emulsions comprising water and volatile organic solvents, followed by freeze drying the emulsion so that by sublimation of both water phase and volatile organic phase the two types of pores may be produced, thereby controlling the porosity of the composite, therefore, it would have been obvious to a one of ordinary skill in the art at the time of the invention was made to combine teachings of **Gregory et al**, **Haynes et al**, **Gross** and **Schneider et al**, i.e. prepare the porous matrix by preparation of an oil-in-water emulsion comprising volatile organic solvent first, followed by freeze drying the emulsion, as taught by **Haynes et al**, in the process of **Gregory et al** so that the porous article of **Gregory et al** will comprise two types of pores and controlled porosity as well, thus arriving at the present invention. Since the porous moulded bodies of **Gregory et al** in view of **Haynes et al** are identical to those claimed in the instant invention and are produced by freeze drying of an oil-in water emulsion containing a hydrophobic drug, therefore, the porous bodies of **Gregory et al** in view of **Haynes et al**, **Gross** and **Schneider et al** will intrinsically contain pores of two types, i.e. produced from sublimation of solid ice from water phase and from sublimation of oil phase and, further will have an intrusion volume as claimed in the

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instant invention, as well. "Products of identical chemical composition can not have mutually exclusive properties" (See MPEP 2112.01).

12. Though **Gregory et al** in view of **Haynes et al**, **Gross** and **Schneider et al** do not explicitly recite the porous composite being produced from complete sublimation of water phase and oil phase, however, since the porosity of the composite depends on the level of removal of water and volatile organic phase, which in turn depend on the time and conditions for sublimation, therefore, sublimation time and conditions such as vacuum, become result effective variables, and therefore, it would have been obvious to one skilled in the art at the time of the invention was made, to make variations in the sublimation time and sublimation conditions such as vacuum to obtain the desired porosity of the composite. *In re Boesch*, 617 F.2d 272, 205 USPQ 215 (CCPA 1980) (MPEP 2144.05 II).

13. Since both **Gregory et al** and **Haynes et al** stated that the surfactant (or emulsifiers) aid in dispersion of the chemical and prevents the freeze dried product from sticking to mold (see col. 4, lines 1-8 of **Haynes et al**) and **Schneider et al** teach the use of surfactants to stabilize the emulsion (col. 4, lines 34-48), therefore, the specific amount of the surfactant present in the composition becomes a result effective variable, therefore, it would have been obvious to one skilled in the art at the time of the invention was made, to make variations in the content of the surfactant to obtain the desired

degree of dispersing of the chemical in aqueous medium and desired stability of the emulsion. *In re Boesch*, 617 F.2d 272, 205 USPQ 215 (CCPA 1980) (MPEP 2144.05 II).

14. Claim 21 is a product by process claim. For purposes of examination, product-by-process claims are not limited to the manipulation of the recited steps, only the structure implied by the steps. See MPEP 2113. In addition, claim 21 teaches an intended use for the porous bodies of instant claim 1. Case law holds that a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. See *In re Casey*, 152 USPQ 235 (CCPA 1967) and *In re Otto*, 136 USPQ 458, 459 (CCPA 1963).

15. Claims 1, 3-9, 21 are rejected under 35 U.S.C. 103(a) as being unpatentable over **Gregory et al** (US 4,371,516) in view of **Haynes et al** (US 5,660,857), **Gross** (US 5,354,290) and **Schneider et al** (US 6,403,057) in further view of **Gole et al** (US 5,648,093), and **Fujimoto** (JP 01011141).

16. The discussion with respect to **Gregory et al** (US 4,371,516) in view of **Haynes et al** (US 5,660,857), **Gross** (US 5,354,290) and **Schneider et al** (US 6,403,057). set forth in paragraphs 4-14 above, is incorporated here by reference.

17. Gregory et al in view of **Haynes et al**, **Gross** and **Schneider et al**

do not explicitly teach the specific ratio between the polymer and a surfactant.

18. Gole et al discloses a fast dissolving solid porous dosage form comprising:

A) 0.1-15% wt of matrix material (col. 2, lines 54-63) comprising hydroxyethylcellulose, sodium carboxymethylcellulose and xanthan gum (col. 6, lines 35-67);

B) a surfactant (col. 6, lines 8-10);

C) an active agent,

wherein an active agent comprises a water-insoluble pigment (col. 13, lines 30-45) and the dosage is produced by lyophilization process (col. 2, lines 54-55).

The specific example discloses spheres produced by freeze drying of an aqueous solution containing 4%wt of a gelatin (as a polymer carrier); 3% mannitol and 1% of sodium diethylsulfosuccinate as a surfactant (col. 15, lines 65-67; col. 1, lines 1-15).

Since no other ingredients besides gelatin (as a polymer carrier); mannitol and sodium diethylsulfosuccinate, therefore, it would have been obvious to a one of ordinary skill in the art at the time of the invention was made that the ratio between these components will be: 12.5 parts of surfactant to 87.5 parts of polymer (gelatin and mannitol).

19. Fujimoto discloses porous article produced from a mixture of 0.05-50% of a hydrophilic polymer (such as cellulose or polyvinyl alcohol) and 0.5-50% of a surfactant, by freeze drying the mixture, wherein the product has a thickness of 5-100mm (Abstract) and the pores are adjustable by the amount of a surfactant (Abstract).

20. Since

1) **Gregory et al** in view of **Haynes et al**, **Gross** and **Schneider et al** disclose shaped articles having a porous open matrix network of water-soluble carrier, the articles carrying a chemical and being rapidly disintegrated by water comprising a polymer and a surfactant, but do not teach the specific ratio between the polymer and a surfactant; **Gole et al** discloses a fast dissolving solid porous dosage form comprising 0.1-15% wt of matrix material comprising hydroxyethylcellulose, a surfactant and an active agent, wherein the ratio between the surfactant and the polymer being 12.5 parts of surfactant to 87.5 parts of polymer; the resulting preparation exhibits high porosity (col. 4, lines 24-27); **Fujimoto** disclose highly porous body produced by freeze drying method, specifically teaching that surfactant is used a pore controlling agent to maximize pore volume (Abstract in **Fujimoto**); therefore, it would have been obvious to a one of ordinary skill in the art at the time of the invention was made to use to combine teachings of **Gregory et al** in view of **Haynes et al**, **Gross** and **Schneider et al** with teachings of **Gole et al** and **Fujimoto** and to use the surfactant also as a pore controlling agent during the process of making porous composites of **Gregory et al** in view of **Haynes et al**, **Gross** and **Schneider et al** as well and further to adjust the specific ratio between the polymer and surfactant to produce porous bodies of **Gregory et al** in view of **Haynes et al**, **Gross** and **Schneider et al** having desired pore volume as well. *In re Boesch*, 617 F.2d 272, 205 USPQ 215 (CCPA 1980) (MPEP 2144.05 II).

21. Claims 1, 3-9, 21 are rejected under 35 U.S.C. 103(a) as being unpatentable over **Yanagibashi et al** (JP-55082621, based on an English translation provided by Applicant in IDS filed on March 18, 2011).

22. As to instant claim 1, Yanagibashi et al discloses a sponge-like porous material having uniform number of holes and hole sizes produced by a) dissolving in water a water-soluble high molecular substance, emulsifier, multivalent alcohol if necessary, b) producing an oil phase comprising a volatile organic solvent together with medical substance; c) adding oil phase to water phase to prepare an oil-in-water emulsion; d) freeze drying the oil-in-water emulsion to produce a desired sponge by perfectly volatilizing the solvent thereupon (Abstract).

The porous material may be in the form of particles (p. 6, lines 10-15), sheet or film (p. 5, lines 20-25) which appear to be molded articles.

The volatile solvent comprises cyclohexane, chloroform, n-hexane, heptane (p. 4, lines 23-27). The example 1 shows the sodium carboxymethylcellulose being used in amount of 2.0%wt and polyoxyethylene sorbitane monooleate being used in amount of 2.0%wt (p. 6, lines 37-40), therefore, it would have been obvious to a one of ordinary skill in the art that the ration of polymeric material to surfactant is 1:1.

Though **Yanagibashi et al** does not explicitly recite the intrusion volume of the porous material, and the pores being produced from complete sublimation of water phase, nevertheless, since the porous bodies of **Yanagibashi et al** comprise the same composition, i.e. the same water-soluble polymeric material, surfactant, the same

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volatile organic solvents as cited in the instant invention (see p. 10, lines 25-30), are produced by the same process including forming oil-in-water emulsion followed by freeze drying the emulsion, therefore, the porous bodies of **Yanagibashi et al** will intrinsically have the intrusion volume identical to that as claimed in the instant invention and will also have pores produced by complete sublimation of water phase as well, especially since **Yanagibashi et al** explicitly recites the pores being produced from “perfectly” volatilizing the solvent (Abstract), and water having boiling point of 100°C will “perfectly” sublime along with organic solvent (such as heptane having boiling point of 98°C).

23. As to instant claims 3-4, the high molecular substance comprises methyl cellulose and polyvinyl alcohol (Abstract; p. 3, lines 12-36).

24. As to instant claims 5-6, the emulsifier comprises polyoxyethylene sorbitan fatty acid esters (p. 4, lines 3-16).

25. As to instant claims 7-9, the porous bodies are used in drug applications, such as vehicle for drugs, wherein the drug may be water-soluble or oil-soluble, i.e. hydrophobic (p. 4, lines 32-37, p. 5, lines 6-10).

26. Claim 21 is a product by process claim. For purposes of examination, product-by-process claims are not limited to the manipulation of the recited steps, only the structure implied by the steps. See MPEP 2113. In addition, claim 21 teaches an intended use for the porous bodies of instant claim 1. Case law holds that a recitation of the intended use of the claimed invention must result in a structural difference between the claimed

invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. See *In re Casey*, 152 USPQ 235 (CCPA 1967) and *In re Otto*, 136 USPQ 458, 459 (CCPA 1963).

Therefore, instant claims 1, 3-9, 21 are obvious over **Yanagibashi et al.**

Response to Arguments

27. Applicant's arguments filed on March 18, 2011 have been fully considered. It is noted that in light of the amendment all previous rejections are withdrawn, thus rendering Applicant's arguments moot. The new grounds of rejection based on the previously applied prior art but suitably framed to better address the newly introduced limitations and Applicant's arguments, are set forth above.

28. Regarding the rejection of claims 1, 3-9, 21 under 35 U.S.C. 103(a) as being unpatentable over **Gregory et al** (US 4,371,516) in view of **Haynes et al** (US 5,660,857), **Gross** (US 5,354,290) and **Schneider et al** (US 6,403,057) and Claims 1, 3-9, 21 under 35 U.S.C. 103(a) as being unpatentable over **Gregory et al** (US 4,371,516) in view of **Haynes et al** (US 5,660,857), **Gross** (US 5,354,290), **Schneider et al** (US 6,403,057) in further view of **Gole et al** (US 5,648,093), and **Fujimoto** (JP 01011141), Applicant argues that while **Gregory et al** does mention the use of the co-solvent, the co-solvent being used to improve the solubility of the chemical, the only mentioned are water-miscible alcohols that would not form an emulsion when added to

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the aqueous polymer solution; **Gregory et al** does not provide any guidance relating to porous bodies having oil-in-water emulsion-formed lattice; co-solvents are "water-miscible organic solvents" and "co-solvent" would not have envisioned a water-immiscible solvent such as an oil. **Haynes et al** discloses composites prepared by drying emulsion to remove water only; the final product still contains oleaginous material. There is no motivation to combine **Gregory et al** and **Haynes et al**.

29. Examiner disagrees.

1) Though **Gregory et al** does not explicitly recite the porous bodies comprising oil-in-water emulsion-formed lattice, it is noted that the limitation of claim 1 "oil-in-water emulsion-formed lattice" is a product by process limitation. For purposes of examination, product-by-process claims are not limited to the manipulation of the recited steps, only the structure implied by the steps. See MPEP 2113. In the present case, the recited steps imply a structure having porous bodies containing hydrophobic material. The reference suggests such a product.

2) **Haynes et al** further teaches that composites containing low quantities of oleaginous material are made by dissolving the oleaginous material in a volatile organic solvent such as n-hexane, wherein the volatile organic solvent is then lost during drying process (col. 3, lines 57-62). Thus, given the very low quantities of oleaginous material are desired, the emulsion of **Haynes et al** will comprise mainly water and volatile organic solvent. Further, since volatile solvent will be lost during freeze drying process thus leading to the formation of pores in the composite, therefore, depending on the relative

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proportion of the oleaginous material, volatile solvent and water, the composite having the desired level of porosity and desired amount of residual oleaginous material may be obtained. Therefore, the relative proportion between the oleaginous material and volatile solvent becomes a result effective variable, and thus, it would have been obvious to one skilled in the art at the time of the invention was made, to make variations in the relative proportion of the oleaginous material and volatile solvent to obtain the composite having the desired porosity and the desired quantity of residual oleaginous material. *In re Boesch*, 617 F.2d 272, 205 USPQ 215 (CCPA 1980) (MPEP 2144.05 II).

3) Further, the newly introduced prior art references of **Gross** and **Schneider et al** teach the porous articles being produced from an oil-in-water emulsion wherein the oil phase of the emulsion comprised the volatile organic solvent, and which emulsion was subjected to freeze drying to sublimate both water and volatile organic solvent phase leading to formation of pores. Thus, since the process of **Gross** and **Schneider et al** disclose the formation of two types of pores thus allowing control of porosity of the final composite, therefore, it would have been obvious to a one of ordinary skill in the art to use the freeze drying of the oil-in-water emulsion in the process of making porous composite of **Gregory et al** as well to ensure formation of two types of pores having specific quantity and size.

4) Furthermore, in the instant invention the critically of the formation of emulsion comprising organic solvent as discontinuous phase is not obvious.

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Specifically, in Table 3 on page 14 of instant specification, an example showing no cyclohexane (0% discontinuous phase) is recited as having intrusion volume of 12.38 ml/g and dissolution time at 20°C of 2.33 min whereas an example showing the use of 40% discontinuous phase is having dissolution time at 20°C of 1.80 min which is only slightly less than in example with no discontinuous phase at all. Further, in Table 4, page 19, an example showing no use of discontinuous phase has dissolution rate of 1.0 min at 20°C which is less than that of the example showing the use of 10% of discontinuous phase (1.1 min) while the intrusion volume for both example was very close (6.38 ml/g and 6.10 ml/g). Similar observations were made regarding results in Table 9 on page 23. The comparison of the inventive examples is made only to commercial polyvinyl alcohol having dissolution time of about 23 min (p. 18, lines 1-4) and commercial SCMC having dissolution rate of 31 min at 20°C (p. 15, lines 1-5). Therefore, the critically of making the porous articles of instant invention by making an oil-in-water emulsion using volatile organic solvent as oil phase is not shown.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to IRINA KRYLOVA whose telephone number is (571)270-7349. The examiner can normally be reached on Monday-Friday 8:00am-5pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Vasudevan Jagannathan can be reached on (571)272-1119. The fax phone

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number for the organization where this application or proceeding is assigned is 571-273-8300.

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/Irina Krylova/
Examiner, Art Unit 1764

/Vasu Jagannathan/
Supervisory Patent Examiner, Art Unit 1764